REMARKS

The Amendments

Claim 33 is amended to clarify that the substance may be one which reduces the lipid content of the adipose tissue in addition to those which eliminate or prevent formation if the adipose tissue. Support for this clarification is found in the specification at, for example, page 18, first full paragraph, and the paragraph, bridging pages 1-2 which states that the disclosure regarding TNF-α applies to the other substances contemplated according to the invention. The claims dependent on claim 33 are amended accordingly. New claims 51-60 are added to provide specific embodiments directed towards the elected species. Some dependent claims are canceled to save extra claim fee costs.

The above amendments do not narrow the scope of the claims and/or were not made for reasons related to patentability. The amendments should not be interpreted as an acquiescence to any objection or rejection made in this application.

To the extent that the amendments avoid the prior art or for other reasons related to patentability, competitors are warned that the amendments are not intended to and do not limit the scope of equivalents which may be asserted on subject matter outside the literal scope of any patented claims but not anticipated or rendered obvious by the prior art or otherwise unpatentable to applicants. Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

The Restriction Requirement

Pursuant to the restriction requirement set forth in the Office Action, applicants hereby elect Group III, drawn to methods for eliminating or reducing normal but undesired adipose tissue in a patient by administering a small molecule drug, such as a beta-adrenergic stimulator substance. It is believed that claims 33, 35, 36, 38, 40, 42 and 46-60 encompass embodiment within the elected invention. The election is made with traverse for the reasons set forth below. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter.

Applicants respectfully submit that the restriction is not properly made under MPEP §806.05(j), as alleged in the Office Action, because – as admitted in the Office Action – the

application contains a linking claim, claim 33, linking the alleged divisible claims. When there is such a linking claim, MPEP §806.05(j) specifically indicates that restriction must be assessed per MPEP §809. Additionally, the two-way distinctiveness requirement of MPEP §806.05(j) is not believed to be met. There is no showing or convincing argument that the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. The fact that the linking claim 33 is generic to all the alleged Groups of invention and recites a unitary design, mode of operation, function, and effect is believed to make clear that the requirements for restriction according to MPEP §806.05(j) are not met.

Regarding MPEP §809, it is acknowledged that restriction can be proper even when a linking claim exists, however, there should be showing made that the linking claim is not allowable over the prior art and such is not provided here. It is also noted that should the linking claim not be rejected over the prior art, the restriction should be withdrawn.

For the above reasons, therefore, it is urged that the restriction requirement is not supported and should be withdrawn.

The Election of Species Requirement

Pursuant to the requirement for an election of species in the Office Action, applicants hereby elect the species of beta-adrenergic stimulators as the small molecule species. It is believed that claims 33, 35, 36, 38, 40, 42 and 46-60 encompass the elected species.

The Examiner is encouraged to examine the broadest possible scope of invention indicated by the elected species. In accordance with M.P.E.P. §803.02, the Examiner is reminded that, should no prior art be found which renders the invention of the elected species unpatentable, the search of the remainder of the generic claim(s) should be continued in the same application. It is improper for the PTO to refuse to examine in one application the entire scope of the claims therein unless they lack unity of invention. The generic claims herein have not been alleged to lack unity of invention.

The Previous Prior Art Rejections

To the extent the prior art rejections from the previous prosecution may be reconsidered, applicants respectfully urge that the cited prior art does not anticipate or render obvious the claimed invention and certainly not the elected species of the claimed invention.

To summarize, Goldenberg fails to disclose a method wherein the controlled release formulation is injected "into the adipose tissue" and the "adipose tissue at a local area such that undesired adipose tissue in the local area is selectively eliminated or reduced." All the teachings in Goldenberg relate to administration of a sustained-release formulation to achieve general/systemic effects on the patient, for example, overall weight loss. For example, in all the embodiments referring to Goldenberg's anti-obesity methods, the results are discussed in terms of overall weight of the patient (or animal model, see, e.g, page 22) and not in terms of the loss of tissue in any particular local area, particularly not in the local area into which the drug is administered. There is no disclosure or suggestion from Goldenberg that elimination or reduction in tissue occurs in the local area of the injection exclusively or to a significantly higher degree than other areas of the body not subject to the injection, i.e., it does not occur "selectively" at the local area of administration. Further, all of the Goldenberg examples involve subcutaneous administration, i.e., under the skin, and no disclosure or suggestion of injection into adipose tissue.

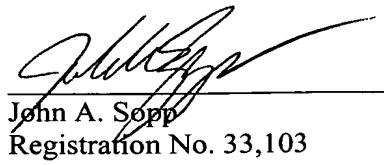
Each of the Hutchinson, Ogawa, Merwin or Johnson articles and Silvestri (U.S. Patent No. 5,126,147) also relate only to systemic delivery of drugs to achieve a general effect. There is no suggestion in any of the references that a specific local area of adipose tissue could be targeted by injection directly into the adipose tissue and that selective reduction of the adipose tissue in that local area could be achieved, as opposed to a systemic effect. Further, there is no suggestion from any of the secondary references for administration by "injection into the adipose tissue."

As to the elected species, the previously relied on prior art also fails to disclose or suggest methods using a beta-adrenergic stimulator substance. Thus, the prior art is further distinguished as to this feature; see, e.g., new claims 51-60.

Favorable action is earnestly solicited. It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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